

## REMARKS

This Response is being filed concurrently with a Request for Continued Examination. Accordingly, entry of the amendments identified herein, and consideration of the remarks below, is respectfully requested.

Additionally, an Information Disclosure Statement citing references cited in co-pending, commonly assigned U.S. application Serial No. 11/411,531, is submitted herewith.

### Status of Application

Claims 1-4 and 6-18 are pending in the application, with claim 13 withdrawn from consideration at this time. Claims 1-4, 6, 8, 10-12, and 14-18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Fischer (U.S. 4,836,217) in view of Peck (U.S. 4,821,733), and claims 7 and 9 stand rejected as being unpatentable over Fischer in view of Peck and Lipper (WO 02/076379).

With this response, claims 1-4 and 6-18 are amended to patentably distinguish over the prior art of record. Claims 19-23 are newly added. No new matter is added by amendment. Support for new claim 19 may be found, for example, at [0042] of the corresponding publication of the instant application (U.S. 2004/0047902). Support for new claim 20 may be found, for example, at [0046]. Support for new claims 21 and 22 may be found, for example, at [0030]. Support for new claim 23 may be found, for example, at [0032] and [0060]. After entering the amendments identified herein, claims 1-4 and 6-23 will be pending in the application.

### Response to Claim Rejections

Claims 1-4, 6, 8, 10-12, and 14-18 stand rejected under 35 U.S.C. §103(a) as unpatentable over Fischer (U.S. 4,836,217) in view of Peck (U.S. 4,821,733); claims 7 and 9 stand rejected as unpatentable over Fischer in view of Peck and Lipper (WO 02/076379).

Applicants have carefully studied the rejections set forth in the Office action, and have amended claims 1 and 14 to patentably distinguish over the prior art of record. In particular,

claim 1 has been amended to recite “a preselected amount of biologically active substance in the form of individualized or agglomerated particles, *the entire preselected amount* of biologically active substance bound to the support within the chamber *solely* by electrostatic forces.” Claim 14 similarly has been amended to recite “an allergen in the form of individualized or agglomerated particles, *all* of the allergen bound to the first surface portion of the support *only* by electrostatic forces.” As described in the corresponding publication of the present application, U.S. 2004/0047902, for example, at paragraphs [0025], [0028], and [0030], the use of *only* electrostatic forces to bind the biologically active substance to the support overcomes the problems with previously-known devices “by maintaining allergens of organic origin in their reactogenic state of origin.”

By contrast, the prior art skin patches cited in the rejections are of the very kinds of previously-known skin patches described in paragraphs [0011] and [0024] of the present application *as representative of the problems encountered in previously-known patches*:

- like the FINN CHAMBERS® described in paragraph [0011], detector means 12 of Peck includes a “porous carrier 16 formed of filter paper which is saturated with the detector chemical” (col. 6, lines 1-11);
- Fischer is specifically identified in paragraph [0024] of the present application as disclosing an allergen uniformly distributed *within* a film-forming material that is evenly and reproducibly deposited on a film carrier (col. 5, lines 45-48). Indeed, claim 1 of Fischer concisely summarizes that invention, claiming “a film-forming polymer *which has incorporated therein* a contact allergy test substance...”

Applicants respectfully submit that no amount of “commercialization optimization” would have led one of ordinary skill in the art, at the time that present application was filed, to either omit the *porous carrier* of Peck or the *film-forming material* of Fischer.

While the use of corona discharge is described in Fischer, at col. 5, lines 48-56, as a commonly used method of enhancing hydrophilicity of a polyester film *substrate* so that *the film incorporating the allergen* would *stick to the substrate better*, there is no hint in Fischer that the

corona discharge could be used *entirely in lieu of* the firm-forming material in which the allergen is incorporated.<sup>1</sup>

Applicants note that even assuming *arguendo* that an infinitesimal amount of substance could conceivably stick to the porous carrier of Peck or the sticky gel-like film of Fischer by electrostatic forces, such an occurrence would not meet the positive limitation of the claims that “the *entire* preselected amount of the biologically active substance” (claim 1) or “*all of* the allergen” (claim 14) is bound to the support “*solely by*” (claim 1) or “*only by*” (claim 14) electrostatic forces. Accordingly applicants submit that claims 1 and 14 patentably distinguish over the prior art.

Applicants note that a statement at page 3 of the Office action appears to suggest that perspiration will *contribute* to electrostatic forces within the prior art Fischer patch:

Perspiration, which contributes to the electrostatic forces within the dermal patch will naturally form a film. The limitation drawn to free particles is acknowledged but whether it begins in the form of free particles or embedded, electrostatic forces and physiological changes on upon the dermis, i.e., temperature and perspiration will achieve the same effect as being claimed.

The opposite is true for the present invention, since the patch is configured such that when it is applied to a patient’s skin, perspiration *releases* the particles from the support to which it was electrostatically bound. Accordingly, to the extent that the Office action sees perspiration as somehow “contributing” to electrostatic forces in Fischer, such an effect is irrelevant and indeed counterproductive in the context of the present invention.

Thus, for at least the reasons given above, neither amended claim 1 nor 14, nor any claim depending therefrom, is obvious over Fischer in view of Peck. Lipper, which is cited as merely disclosing a medicated tattoo, does not cure the deficiencies of Fischer and Peck.

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<sup>1</sup> Fischer emphasizes the criticality of achieving a uniform distribution of the allergen *in the polymer film*: There are two *important* steps in the manufacturing procedure which are of *prime importance* for the result obtained: (1) the test allergen *has to be* distributed uniformly in the film-forming material. (2) The film carrier *has to be* coated reproducibly with a film of even thickness (col. 5, lines 43-48, emphasis added). This teaching is antithetical to the suggestion that the film-forming material could be *omitted*.

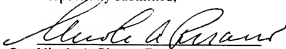
**Conclusion**

For at least the reasons given above, applicants submit that this application is condition for allowance. Applicants request that the Examiner call the undersigned if a telephone call could help resolve any remaining items.

No fees are believed due at this time. However, please charge any required fees, or credit any overpayments, to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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 34,408  
By: Nicola A. Pisano, Esq. (Reg. No.)  
**JONES DAY**  
222 East 41st Street  
New York, New York 10017-6702  
(858) 314-1200